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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,224	10/14/2005	Robert C. Giles	13361 PCT US	9719
23719 7590 04/30/2007 KALOW & SPRINGUT LLP 488 MADISON AVENUE 19TH FLOOR NEW YORK, NY 10022			EXAMINER SHAW, AMANDA MARIE	
			ART UNIT	PAPER NUMBER
			1634	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		04/30/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/519,224

Applicant(s)

GILES ET AL.

Examiner

Amanda M. Shaw

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, drawn to a panel of single nucleotide polymorphisms, classified in class 536, subclass 23.1.
  - II. Claims 3-6, drawn to a method of generating a panel of single nucleotide polymorphisms, classified in class 435, subclass 287.2.
  - III. Claims 7-20, drawn to a method for determining the identity of an individual, classified in class 435, subclass 6.
  - IV. Claims 21-31, drawn to a method genotyping a nucleic acid sample, classified in class 435, subclass 6.
  
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another materially different process such as using a computer program to identify SNPs that are not genetically linked and that are located outside tandem repeat nucleic acid sequences and then synthesizing the sequences using the phosphoramidite method.

Inventions I and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Invention I can be used in a materially different process, such as for synthesizing primers of probes.

Inventions II and III-IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed different process steps and different objective. For example Invention II is drawn to a method of generating a panel of SNPs and requires selecting a panel of two or more SNPs that are not genetically linked to one another and wherein the SNPs of the genome are located outside tandem repeat nucleic acid sequences. Invention III is drawn to a method for determining the identity of an individual and requires obtaining a unknown sample from a person, identifying SNPs in the sample and then comparing the SNPs found with a known sample and determining whether the unknown sample and known sample are derived from the same or related individual. Invention IV is drawn to a method for genotyping and requires obtaining a sample,

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identifying two or more SNPs in the sample, and then comparing the SNPs in the sample with the identities of the SNPs in the panel to determine the genotype.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed different process steps and different objective. For example Invention III is drawn to a method for determining the identity of an individual and requires obtaining a unknown sample from a person, identifying SNPs in the sample and then comparing the SNPs found with a known sample and determining whether the unknown sample and known sample are derived from the same or related individual. Invention IV is drawn to a method for genotyping and requires obtaining a sample, identifying two or more SNPs in the sample, and then comparing the SNPs in the sample with the identities of the SNPs in the panel to determine the genotype. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

**Sequence Election Requirement Applicable to Invention I**

3. The claims have been presented in improper Markush format, as distinct products are improperly joined by the claims. Group I reads on patentably distinct inventions drawn to multiple SEQ ID NOs (see claim 2). Each nucleic acid consists of a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization, and encodes for a protein having a different biological activity. For example, a nucleic acid comprising SEQ ID NO: 25 is chemically, structurally and functionally distinct from a nucleic acid comprising SEQ ID NO: 61. A search for a nucleic acid comprising SEQ ID NO: 25 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 61. Further, a finding that nucleic acid comprising SEQ ID NO: 25, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 61 is also novel and unobvious over the prior art. Similarly, a finding that a nucleic acid comprising SEQ ID NO: 25 is anticipated or obvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 61 is also anticipated or obvious over the prior art. Thus it would pose a serious burden to examine more than one SEQ ID or combination of SEQ IDs.

Accordingly, the oligonucleotides and combinations of oligonucleotides are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, if Applicant elects invention I, the Applicant should further elect a two sequences or a combination of sequences selected from the SEQ ID NOs listed in Claim 2.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-IV require different searches that are not co-extensive. For instance, a literature search for the product of invention I is not co-extensive with a literature search for the methods of inventions II-IV. For instance, a finding that, for example, the product of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the methods of inventions II-IV are also anticipated or obvious over the prior art. Similarly, a finding that the product of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of inventions II-IV are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.



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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

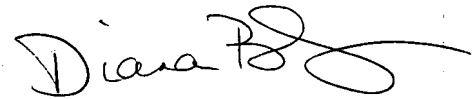
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
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A handwritten signature in black ink, appearing to read "Diana Johannsen", with a stylized flourish at the end.

**DIANA JOHANNSEN  
PRIMARY EXAMINER**